

Appl. No. 10/043,590
Resp./Amdt. dated April 1, 2004
Reply to Office Action of 01/09/2004

REMARKS/ARGUMENTS

There are no amendments to the specification or drawings herein.

In the Claims, Claims 29-37 are pending in the application. Claims 29-35 remain in the instant application as being drawn to an elected invention. Claims 36 and 37 were previously withdrawn from further consideration as being drawn to a nonelected invention. Claims 29-35 are rejected. Reconsideration is respectfully requested.

The Examiner acknowledged Applicant's election with traverse of Group I (Claims 29-35) in Paper dated Oct. 10, 2003. The Examiner found the arguments in support of the traverse to be unpersuasive and refused Applicant's request for rejoinder of Groups II (Claim 36) and Group III (Claim 37) with elected Group I. However for the record, Applicant maintains the traversal and disagrees with the Examiner's reasoning provided in the pending Office Action mailed 1/9/04 for not rejoining Groups II and III with Group I. Applicant is respectfully concerned that the Examiner may have taken Applicant's reasons for traversal out of context in the Examiner's response, because Applicant could not follow the Examiner's rationale for refusing to rejoin. As such, Applicant still maintains that the election requirement is improper.

Claims 29-35 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Moreover, the Examiner specifically indicated that the rejection under 35 U.S.C. 112, first paragraph, was a "written description" rejection.

Applicant respectfully traverses the rejection of Claims 29-35 under 35 U.S.C. 112, first paragraph. Applicant submits that the rejected claims are all as originally filed and described in the specification as filed. No amendments to the claims, specification or drawings have been made. Moreover, there are no terms, elements or limitations present in the rejected claims that have non-conventional or specialized meanings unsupported by definitions in the specification. As such, Applicant submits

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that one skilled in the art would conclude that, at the time the application was filed, the inventors did have possession of the claimed invention with respect to Claims 29-35. A presumption of Applicant's possession of the invention exists. Therefore, it is respectfully submitted that Applicant has met the written description requirement of 35 U.S.C. 112, first paragraph with respect to Claims 29-35 for the reason set forth above and further, for the reasons set forth below.

The Examiner specifically contended with respect to Claim 29, that, "[t]he specification disclosure does not sufficiently teach the method of fabricating a biopolymer array from pre-synthesized biopolymers wherein *the first step* is to 'enclose' the surface of the array in a non-miscible fluid (NMF) and then adding the biopolymer onto the array surface to link the biopolymer to the surface" (emphasize is the undersigned's). The Examiner supported the contention by asserting that "[s]ince the NMF is inert, immiscible and insoluble in aqueous solution, it would prevent the 'attachment' of the biopolymer to the surface".

However with respect to Claim 29, the Examiner did not provide any specific evidence or other reasoning in support of the NMF 'preventing' the attachment of the biopolymer to the surface, as contended by the Examiner. Instead, the Examiner referred to page 7, lines 8-20 of Applicant's specification (i.e., the 'Summary of the Invention') to contend that the specification was directed to a method of fabricating a biopolymer array from pre-synthesized biopolymers wherein the droplets of the deprotected pre-synthesized biopolymer solution is enclosed in the NMF before depositing onto the array surface. As such, the Examiner concluded that the specification did not teach that recited in Claim 29. It appears that the Examiner has relied on the description of an embodiment on page 7, lines 8-20 in the 'Summary' for this rejection under the written description requirement apparently without reading or considering the 'Detailed Description of the Invention' starting on page 17 of Applicant's specification and in particular, pages 26-29 of the 'Detailed Description'.

Applicant earnestly disagrees with the Examiner's contention and assertion regarding Claim 29. While Claim 29 recites "adding a non-miscible fluid (NMF) to the array surface, the NMF being inert, immiscible and insoluble in aqueous solution" and "depositing the biopolymer solution on the array surface and linking the

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biopolymer to the surface", the claim is silent on whether adding the NMF to the array surface precedes or follows depositing the biopolymer on the array surface.

Therefore, Claim 29 broadly covers both situations. While it is understood that the Examiner must consider the broadest interpretation of a claim, for the record, "adding a non-miscible fluid ..." precedes (or '*is a first step*', as contended by the Examiner) "depositing the biopolymer ..." in *only some embodiments*. (Emphasis is provided for the Examiner's convenience.)

Moreover, Claim 29 is fully supported by the specification as filed. The Examiner is directed to page 27, approx. line 22 to page 28, line 10 of Applicant's specification, for example, where the method 200 is described in part. In particular, at page 28, lines 5-6, the specification states "[a]ny of the deposition methods illustrated in Figures 2 to 6a,b will work for the method 200". Therefore, the description of Figures 2 to 6a, 6b with reference to the method 100, 100' using biomonomers in Applicant's specification as filed applies to the method 200 directed to pre-synthesized biopolymers. One skilled in the art would clearly realize this from that already stated in the specification as filed.

As such, Applicant provides numerous examples of depositing the biopolymer solution on the array surface and linking the biopolymer to the surface in the presence of the NMF in the Applicant's specification as filed. For example, Figures 2-6a illustrate several embodiments in which a pulsejet head delivers or 'fires' droplets of biopolymer into the NMF (again see discussion on page 27, approx. line 22 to page 28, line 10, and in particular, page 27, approx. line 29 to page 28, line 5 of Applicant's specification).

Figures 2-4 clearly illustrate the biopolymer droplets 28 being deposited into the NMF and moving in a downward direction from the pulsejet head, through the NMF and to the sites 22 or feature locations on the surface 23 of the array 20 (see pages 20-23 of Applicant's specification). Moreover, Figure 5 illustrates an embodiment in which the biopolymer droplets 28 move in an upward direction from the pulsejet head 26, through the NMF, and to the sites 22 or feature locations on the surface 23 of the array 20 (see page 23, approx. lines 6-15 of Applicant's specification). In Figure 6a, an embodiment is illustrated in which the biopolymer droplet 28 is fired from the

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pulsejet head into individual droplets 31 of NMF that surround or envelop one or more individual biopolymer synthesis sites 22. Figure 6b clearly illustrates the biopolymer droplet 28 in contact with the site 22 on the surface 23 of the array 20 (see page 23, approx. lines 16-27 of Applicant's specification).

As discussed in the specification, movement of the biopolymer droplets through the NMF may be aided by one or more of a *speed with which the droplet is ejected* from the deposition system (see for example, Applicant's specification at page 20, approx. lines 11-13 and page 24, approx. lines 19-22); *a differential density between the NMF and the biopolymer droplets* (see for example, Applicant's specification at page 23, approx. line 29 to page 24, approx. line 17 and page 24, approx. lines 22-24); and *surface tension of the different fluids* as well as *the deposition system used* (see for example, Applicant's specification at page 24, approx. lines 17-19)). Also see again, page 27, approx. line 22 to page 28, line 10 of Applicant's specification. (Emphasis is provided above for the Examiner's convenience.) In addition as described in the specification, the sites may be treated or prepared in a manner known in the art that promotes linking of the biopolymer to the site to further insure that once the biopolymer droplet has reached the site, the NMF will not impede linkage thereto (see for example, Applicant's specification at page 27, lines 3-8).

Whether aided by the preparation or treatment of the sites in a manner known in the art that promotes linkage or not, linkage of the biopolymer to the site occurs when the droplets moving through the NMF displace the NMF from the site. In other words, the displacement of NMF allows the biopolymer droplet to contact the site when NMF is originally present at the site prior to deposition of the droplet. Note also that the NMF is essentially 'displaced' from the site in embodiments where the biopolymer is 'deposited' prior to 'adding' the NMF since the biopolymer droplet is present at the site first. In fact, explicit in the present invention is that the inert NMF does not interfere with linking of the biopolymer to the array but instead merely "impedes or delays the diffusion and subsequent evaporation of the aqueous solution, so that the linkage reaction can be completed" (see for example, page 28, approx. lines 14-17 of Applicant's specification).

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Applicant respectfully points out to the Examiner that there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. The court has held in part, "[T]he PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *In re Wertheim*, 541 F.2d 257, 262-263, 191 USPQ 90, 96-97 (CCPA 1976). "In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification." *Autogiro Co. of America v. United States*, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967). Also, "[i]t is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification". *In re Wertheim*, cited *supra*.

Furthermore, as stated in the MPEP 2163 "[w]hat is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient")." As such, Applicant submits that the specification, drawings, and Claims 29-35 themselves, being as originally filed, provide more than enough to meet the written description provision of 35 U.S.C. 112, first paragraph, notwithstanding the Examiner's apparent unfamiliarity with aspects related to the invention that are known in the art.

As to the Examiner's specific, albeit erroneous, assertion that "[s]ince the NMF is inert, immiscible and insoluble in aqueous solution, it would prevent the 'attachment' of the biopolymer to the surface", the Examiner provides no evidence or other reasoning in support thereof. In fact, the Examiner merely makes a broad conclusory statement that such 'attachment' would be prevented by the NMF.

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Applicant respectfully reminds the Examiner that, as stated and affirmed numerous times by the courts, "[b]road conclusory statements ... standing alone, are not 'evidence'". See e.g., *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1578, 27 USPQ2d 1129, 1131 (Fed. Cir. 1993). Furthermore, the examiner may not "resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis." *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied 389 U.S. 1057 (1998). It is respectfully submitted that without evidence, the Examiner's broad conclusory statement that the NMF would prevent biopolymer attachment is unsupported.

Moreover, Applicant explicitly refutes the Examiner's assertion and, barring a showing of such evidence by the Examiner, respectfully submits that the Examiner's assertion does not support the rejection. As such, the Examiner does not present a *prima facie* case that Claim 29 does not meet the written description requirement of 35 U.S.C. 112, first paragraph. Claims 30-35 ultimately depend from Claim 29 and the Examiner has not cited any grounds beyond those applied to Claim 29 to reject Claims 30-35 under 35 U.S.C. 112, first paragraph. As such, the rejection of Claim 29 as well as Claims 30-35 under 35 U.S.C. 112, first paragraph, is unsupported and must be withdrawn. Reconsideration is respectfully requested.

Claims 29-35 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner stated, "[i]t is unclear as to how the biopolymer is link [*sic*] to the surface when the surface is "cover" [*sic*] with the non-miscible fluid (NMF) as claimed in claim 29 because as define [*sic*] in the specification (pg. 19, line 10-11) that "*the NMF does not chemically react with the biomonomer, reagents, anhydrous solvent or other ancillary materials*" (e.g. inert) (emphasis is the Examiner's). The Examiner further stated, "[i]t is unclear how the biopolymer solution is deposited on the array surface *through* the NMF as claimed in claims 30, 32, and 34-35 because as define [*sic*] in claim 29 the NMF is immiscible and insoluble in aqueous solution" (emphasis is the Examiner's).

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Applicant traverses the rejection of Claims 29-35 under 35 U.S.C. 112, second paragraph. In particular, the inert characteristics of the NMF essentially insure that the NMF does not interfere with the droplets of biopolymer or the attachment of thereof to the array surface. One skilled in the art would certainly appreciate that, in the very least, using an NMF that is inert essentially prevents or minimizes any such interference. Moreover, as is well known in the art, linkage of the biopolymer to the surface is a function of the characteristics of the biopolymer and the surface. As stated in Applicant's specification at page 28, approx. lines 14-18, "[t]he NMF effectively shields each droplet 28' and impedes or delays the diffusion and subsequent evaporation of the aqueous solution, so that the linkage reaction can be completed. As a result, the deposited pre-synthesized biopolymers 28' have uniform concentration throughout each feature location 22".

Furthermore as noted hereinabove, Applicant has provided numerous examples and/or embodiments describing how the biopolymer solution is deposited on the array surface through the NMF. For example, the Examiner is directed to the discussion hereinabove and in Applicant's specification regarding using a pulsejet head and employing density differences (again see for example, page 24, lines 12-29). As an analogy for the Examiner's benefit only and in no way by limitation herein, the immiscibility and insolubility of the NMF in aqueous solution is no more of an impediment to the movement of the biopolymer droplets through the NMF than the movement of the so-called 'lava' substance in the suspending fluid of a Lava Lamp®, or the movement of a drop of water through oil, such as in an 'oil and water' salad dressing, for example.

In short, there simply is no lack of clarity regarding the inert nature of the NMF or the movement of the biopolymer through the NMF and deposition of the biopolymer on the surface of the array in the presence of the NMF, as contended by the Examiner. One skilled the art simply would not find such issues raised by the Examiner exist given Applicant's specification and claims, as originally filed. Without supporting evidence to the contrary from the Examiner, Applicant is at a loss to respond further.

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Moreover, Applicant respectfully suggests that the Examiner's contention of lack of clarity is not actually 'indefiniteness', as defined by 35 U.S.C. 112, second paragraph, but perhaps something else not related to the instant application for patent. In 35 U.S.C. 112, second paragraph, an applicant must in the claims "set forth the subject matter that an applicant regards as the invention", and "particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant". Applicant believes that Claims 29-35 meet these requirements. Furthermore, it appears that the Examiner is not applying either of these requirements in rejecting Claims 29-35. The Examiner has not stated how Claims 29-35 fail to either "set forth the subject matter" or "particularly point out and distinctly define the metes and bound of the subject matter". Instead, it respectfully appears that the Examiner has stated a 'personal' lack of understanding regarding the claims in question. As such, Applicant respectfully further submits that the Examiner has not properly rejected Claims 29-35 under 35 U.S.C. 112, second paragraph.

Therefore, it is respectfully submitted that the Examiner's rejection of Claims 29-35 as indefinite under 35 U.S.C. 112, second paragraph, is wholly without merit and should be withdrawn. Reconsideration is respectfully requested.

Claim 29 was rejected under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (U.S. Patent No. 5,063,081). The Examiner supported the rejection by stating, in part, "Cozzette et al. disclose a manufacturing method for producing a biosensor ... (col. 19, lines 23-45)", wherein "[t]he method steps comprise of [*sic*] adding a solution of silane mixture (non-miscible fluid (NMF)), which is aqueous as well as water-miscible organic solvent [*sic*] (col. 28, lines 19-23), that form a layer of permselective membrane (col. 13, lines 54-62; col. 29, lines 39-43); and a step of immobilizing the biological active species onto the surface to form an array of biopolymer (col. 31, lines 21-30)."

Applicant traverses the rejection on the grounds that the Examiner had failed to establish a proper case for *prima facie* anticipation with respect to Cozzette et al. In particular, Applicant submits that Cozzette et al. do not disclose each and every element recited in Claim 29 as required to establish a *prima facie* case of anticipation under 35 USC 102.

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Applicant respectfully reminds the Examiner that to maintain an anticipation rejection, the "trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Moreover as stated by the Federal Circuit, "there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripts Clinic & Research Found. V. Genentech Inc.*, 927 F.2d 1565, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991). In particular with respect to establishing *prima facie* anticipation, the Federal Circuit has stated that "anticipation requires the disclosure in a single prior art reference each element of the claim under consideration". *W.L. Gore & Associates v. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). In addition, each element disclosed by the reference must be "arranged as in the claim". *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, *supra*, at 481, 485. Furthermore, while it is permissible in some instances to rely on an inherent characteristic of a device or process to provide a minor aspect of the claimed invention, "inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient". *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA. 1981). Moreover, "if the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of patent". *In re Oelrich*, 977, F.2d 1443, 24 USPQ 2d 1443 (Fed. Cir. 1992).

Specifically, the Examiner contended that "adding a solution of silane mixture ... which is aqueous as well as water-miscible organic solvent" was a disclosure of "adding a non-miscible fluid (NMF) to the array surface, the NMF being inert, immiscible and insoluble in aqueous solution", as claimed in Claim 29. However, the aqueous and water-miscible silane mixture is an explicitly direct contradiction to the NMF being immiscible and insoluble in aqueous solution. Therefore, contrary to that contended by the Examiner, Cozzette et al. do not disclose "adding a non-miscible fluid (NMF) to the array surface, the NMF being inert, immiscible and insoluble in

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aqueous solution", as claimed in Applicant's Claim 29. This difference should be clear to the Examiner.

At Col. 28, lines 33-39, Cozzette et al. do disclose using water-immiscible solvents to prepare the silane mixture. However, such silane mixture, whether prepared with water miscible or water-immiscible solvents, is not "inert", as claimed in Applicant's Claim 29. As mentioned above, Cozzette et al. disclose that the silane mixture is an 'adhesion promoter' or a "coupling reagent" commonly used to "promote adhesion between component layers" (see Col. 28, lines 1-5). As such, Cozzette et al. further do not disclose, "adding a non-miscible fluid (NMF) to the array surface, the NMF being inert, ...", as recited in Applicant's Claim 29.

Therefore, the Examiner has failed to establish a case for *prima facie* anticipation with respect to Cozzette et al. In particular, the Examiner at least has failed to show that there is no difference between the claimed invention and the reference disclosure (*Scripts Clinic & Research Found. V. Genentech Inc.*, cited *supra*). Further, the Examiner at least has failed to show that the reference teaches each and every element of Applicant's claimed invention (*W.L. Gore & Associates v. Garlock*, cited *supra*). Finally, the Examiner has failed to establish that each element is arranged as in the claim (*Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, cited *supra*). Therefore, the rejection of Claim 29 under 35 U.S.C. 102(b) is unsupported and should be withdrawn for at least the reasons set forth hereinabove. Moreover, since a case for *prima facie* anticipation has not been established, then without more, Applicant is entitled to a grant of patent (*In re Oelrich*, cited *supra*).

In summary, Claims 29-37 are pending. Claims 29-35 were rejected. Claims 36 and 37 were previously withdrawn from further consideration as being drawn to a nonelected invention. Claims 29-35 are in condition for allowance. It is respectfully requested that Claims 29-35 be allowed, and that the application be passed to issue at an early date.

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Should the Examiner have any questions regarding the above, please contact the undersigned, Elizabeth E. Leitereg, telephone number (775) 849-3085, or Gordon M. Stewart, Attorney for Applicant, Registration No. 40,026 at Agilent Technologies, Inc., telephone number (650) 485-2386.

Respectfully submitted,

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